REMARKS

Claims 2, 12, 20, 25, 26, 32-36, 38-41, 43-50, and 54 have been canceled without prejudice to pursuing these claims in a different application. Claims 4, 5, 7, 9, 10, 37, and 42 are withdrawn. Claims 1, 3, 8, 11, 13, 15 17, 19, 23, and 24 have been amended. Therefore, claims 1, 3, 8, 11, 13-19, 21-24, 27-31, 51-53, and 55-57 are presented for the examination.

Claim rejections under 35 USC §112, second paragraph

The Examiner rejected Claims 12, 23, 45, 51, 52, 54 and 57 under 35 U.S.C. §112, second paragraph, as being indefinite. More specifically, the Examiner believes that the limitation of a compound or molecule having molecular weight of less than or equal to 500 Da without specifying the method used for measuring the molecular weight renders the claim vague and indefinite. The Applicant respectfully disagrees. Molecular mass measured in daltons is known in the art to be the sum of the atomic masses of all atoms in one molecule of a compound, and therefore can be readily calculated, and not necessarily measured. Where molecules of undetermined composition are concerned, such as proteins, DNA, etc., their molecular masses have to be measured experimentally, and will vary depending on the method employed. However, the present invention describes small lipophilic molecules capable of traversing the stratum corneum. These compounds are distinct from the aforementioned class of molecules having undetermined composition. Indeed, the molecular weights of the compounds described on pages 24-26 in the specification as filed, and recited in the amended claims, can be calculated from the molecular formulas. Therefore, Applicant respectfully asserts that "a lipophilic molecule capable of traversing the stratum corneum and... is ≤500 daltons..." is sufficiently definite under §112, second paragraph.

Claim 23 was found indefinite, as the Examiner did not see how the introduction of the antigen to a portion of the respiratory, urogenital or gastrointestinal tracts is different from the introduction of the antigen to the respiratory, urogenital or gastrointestinal tracts. The Applicant has amended Claim 23 to now recite "delivery to respiratory, urogenital or gastrointestinal tracts".

Accordingly, Applicant respectfully requests withdrawal of the under 35 U.S.C. §112, second paragraph.

Claim rejections under 35 USC §112, first paragraph

The Examiner rejected Claims 25, 26, 32-36, 38-41, 43-50 and 54 under 35 U.S.C. §112, first paragraph, as non-enabled. More specifically, the Examiner did not find enabling disclosure in the specification for an expression vector adapted to induce the prolonged expression of the antigen or epitope thereof. While Applicant does not acquiesce to this rejection and contends that use of such expression vectors, as well as the construction of such vectors, are well within the skill of those in the art (as cited in the specification, pg. 38), Applicant has now canceled claims 25, 26, 32-36, 38-41, 43-50 and 54, without prejudice, in order to pursue claims directed at commercial embodiments of the present invention. Applicant reserves the right Therefore, the Examiner's rejection under 35 U.S.C. §112, first paragraph is now moot.

Claim rejections under 35 USC §102

The Examiner rejected Claims 1-3, 6, 8, 11-16, and 28-31 under 35 U.S.C. §102(b) as being anticipated by Marchal *et al.* (Adv. Exp. Med. Biol. 1995, 378:219-221). To be anticipatory under 35 U.S.C. § 102, a reference must teach each and every element of the claimed invention. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379 (Fed. Cir. 1986). "Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. ...There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." *See Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991).

Marchal *et al.* disclose a method of topical immunization of a mammal by administration of FITC as an allergen dissolved in 50% acetone/dibutylphthalate. However, Marchal *et al.* do not disclose that the antigen or epitope(s) thereof is introduced into the mammal by disrupting the stratum corneum as recited in amended Claim 1. Therefore, Marchal *et al.* cannot anticipate Claims 1-3, 6, 8, 11-16, and 28-31. Accordingly, Applicant respectfully requests withdrawal of this rejection under §102.

The Examiner also rejected Claims 1-3, 7, 8, 11-15, 23, 28-31 and 55-57 under 35 U.S.C. §102(b) as being anticipated by Gizurarson *et al.* (WO 94/17827). Gizurarson *et al.* disclose a method of topical administration of antigens in mammals via mucosal membrane in a

composition that may optionally include benzoic acid. However, Gizurarson *et al.* does not disclose that the antigen or epitope(s) thereof is introduced into the mammal by disrupting the stratum corneum as recited in amended Claim 1. Therefore, Gizurarson *et al.* cannot anticipate any of Claims 2, 3, 7, 8, 11-15, 23, 28-31 and 55-57. Accordingly, Applicant respectfully requests withdrawal of this rejection under §102.

The Examiner also rejected Claims 55 and 56 under 35 U.S.C. §102(b) as being anticipated by King *et al.* (Vaccine, 1987, 5:234-238). King *et al.* disclose a method for vaccinating a mammal against an antigen comprising delivering to nasal passages a topically applied live vaccine. King *et al.* does not disclose each and every element of the claimed invention. For example, King *et al.* fails to teach increasing the number of antigen-bearing dendritic cells in a lymphoid organ, as recited in the amended claims. Therefore, because King et al. cannot anticipate Claims 55-56. Accordingly, Applicant respectfully requests withdrawal of this rejection under §102.

The Examiner also rejected Claims 1, 2, 12, 13, 14, 18, 27-31 and 53 under 35 U.S.C. §102(e) as being anticipated by Glenn *et al.* (USP 5,980,898). Glenn *et al.* disclose a method for vaccinating a mammal comprising an activator of Langerhans cells, wherein said activators are trinitrochlorobenzene, dinitrofluorobenzene, pentadecylcatecol and Lipid A. Trinitrochlorobenzene, dinitrofluorobenzene, pentadecylcatecol are known contact sensitizers, which when applied topically cause contact dermatitis, while Lipid A has a molecular weight of about 1900 Da (monophosphoryl Lipid A, the detoxified version of Lipid A which is pharmacologically acceptable, has a molecular weight of 1955.81), greater than three-times the upper limited of the recited lipophilic molecule. Claim 1 as amended recites: "said lipophilic molecule is ≤ 500 daltons and does not induce contact dermatitis." Thus, Glenn *et al.* does not anticipate amended Claims 1, 2, 12, 13, 14, 18, 27-31 and 53. Accordingly, Applicant respectfully requests withdrawal of this rejection under §102.

The Examiner also rejected Claim 1 under 35 U.S.C. §102(b) as being anticipated by Paul *et al.* (Vaccine Research 1995, Vol. 4:145-164) as evidenced by Roitt *et al.* (Immunology (text), 1993, pp. 8.3-8.4). Paul *et al.* disclose a non-invasive method of vaccinating using topical administration of transferosomes, which are adapted to spontaneously penetrate intact stratum corneum. Amended Claim 1 recites introducing the antigen or epitope thereof by "disrupting the stratum corneum...". Thus, because Paul *et al.* fail to teach each and every element of the

amended claims, Paul *et al.* cannot anticipate these claims. Accordingly, Applicant respectfully requests withdrawal of this rejection under §102.

Obviousness-type double patenting

The Examiner also rejected Claims 1-3, 6-8, 11-16, 51-57 under the judicially created doctrine of obviousness-type double patenting as unpatentable over Claims 1-21 of U.S. Pat. No. 6,210,672. The Applicant acknowledges this rejection and reserves the right to file a terminal disclaimer once pending claims are allowed by the Examiner.

Allowable Claims

The Examiner indicated that Claims 17, 19-22 and 24 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicant has amended the Claims 17, 19, 21, 22, and 24 accordingly, and canceled Claim 20. Thus, these claims are now presented in allowable form.

CONCLUSION

The Applicant has endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. Accordingly, amendments to the claims, the reasons therefor, and arguments in support of the patentability of the pending claim set are presented above. Any claim amendments which are not specifically discussed in the above remarks are made in order to improve the clarity of claim language, to correct grammatical mistakes or ambiguities, and to otherwise improve the capacity of the claims to particularly and distinctly point out the invention to those of skill in the art. In light of the above amendments and remarks, reconsideration and withdrawal of the outstanding rejections is specifically requested. If the Examiner finds any remaining impediment to the prompt allowance of these claims that could be clarified with a telephone conference, the Examiner is respectfully requested to call the undersigned.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 6/19/03

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